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PFIZER INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION *This document relates to* MARCUS ALLUMS, et al., Plaintiffs, vs. PFIZER, INC., Defendant.	MDL Docket No. 1699 CASE NO. 3:07-cv-6088-CRB **PFIZER INC.'S ANSWER TO COMPLAINT** **JURY DEMAND ENDORSED HEREIN**

NOW COMES Defendant Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as "Pfizer, Inc.") ("Pfizer" or "Defendant") and files this Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally. Defendant may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiffs were prescribed and used Bextra®.

II.

ANSWER

Response to Allegations Regarding Jurisdiction and Parties

1. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac. and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

2. Defendant admits that Plaintiffs brought this civil action seeking monetary damages, but denies that Plaintiffs are entitled to any relief or damages. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning the amount in controversy, and, therefore, denies the same. However, Defendant admits that Plaintiffs claim that the amount in controversy exceeds $75,000, exclusive of interests and costs. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

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applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

3. Defendant admits that it is a Delaware corporation with its principal place of business in New York and that it does business in the United States. Defendant denies the remaining allegations in this paragraph of the Complaint.

4. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning Plaintiffs' citizenship and the amount in controversy, and, therefore, denies the same. However, Defendant admits that Plaintiffs claim that the parties are diverse and that the amount in controversy exceeds $75,000, exclusive of interests and costs.

Response to Factual Allegations

5. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' medical condition and whether Plaintiffs used Bextra®, and, therefore, denies the same. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

6. Defendant admits that Bextra® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® throughout the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

7. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® throughout the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

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8. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

9. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

10. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® throughout the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

11. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

12. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

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13. Defendant states that the referenced April 7, 2005 FDA document speaks for itself and respectfully refer the Court to the FDA document for its actual language and text. Any attempt to characterize the document is denied. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph.

14. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Bextra®, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

15. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Strict Liability

16. Defendant incorporates its responses to each paragraph of Plaintiffs' Complaint as if set forth fully herein.

17. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint, including

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all subparts.

18. Defendant states that, in the ordinary case, Bextra® was expected to reach users and consumers without substantial change from the time of sale. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph regarding whether Plaintiffs used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

19. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Bextra®, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

20. The allegations in this paragraph of the Complaint are not directed towards Defendant, and, therefore, no response is required. To the extent a response is deemed required, Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

21. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it has duties as are imposed by law, but denies having breachedhaving breached any such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

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22. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

23. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

24. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

25. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 25 of the Complaint, Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Negligence

26. Defendant incorporates its responses to each paragraph of Plaintiffs' Complaint as if set forth fully herein.

27. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it has duties as are imposed by law, but denies having breached any such duties. Defendant denies the remaining allegations in this paragraph of the Complaint.

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28. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

29. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

30. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

31. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

32. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 32 of the Complaint, Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Negligent Misrepresentation

33. Defendant incorporates its responses to each paragraph of Plaintiffs' Complaint as if set forth fully herein.

34. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information,

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which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.

35. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

36. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

37. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

38. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective

when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

39. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

40. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

41. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it has duties as are imposed by law, but denies having breached any such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

42. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, denies

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that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

43. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

44. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 44 of the Complaint, Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in the unnumbered paragraph following this paragraph of the Complaint.

Response to Fourth Cause of Action: Fraud

45. Defendant incorporates its responses to each paragraph of Plaintiffs' Complaint as if set forth fully herein.

46. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

47. Defendant denies any wrongful conduct and denies the remaining the allegations in this paragraph of the Complaint.

48. Defendant any wrongful conduct and denies the remaining the allegations in this paragraph of the Complaint.

49. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Bextra®, and, therefore, denies the same. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times

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adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

50. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

51. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

52. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

53. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it has duties as are imposed by law, but denies having breached any such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

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54. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

55. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

56. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

57. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

58. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 58 of the Complaint, Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damage, and denies the remaining allegations in this paragraph of the Complaint.

III.

GENERAL DENIAL

Defendant denies all allegations and/or legal conclusions set forth in Plaintiffs'

Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendant reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant affirmatively shows that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant's labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendant, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendant provided proper warnings, information, and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendant's warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed, and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendant.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

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Seventh Defense

7. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiffs and Plaintiffs' damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendant cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendant affirmatively denies that it violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiffs' treating and prescribing physicians.

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Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiffs was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Bextra® by persons other than Pfizer or persons acting on its behalf after the product left the control of Pfizer.

Seventeenth Defense

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendant.

Eighteenth Defense

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Nineteenth Defense

19. Plaintiffs knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendant because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by

the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution, and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f

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to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendant's rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitution of the State of California, and would additionally violate Defendant's right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by and the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendant.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

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Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitution of the State of California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of

punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured, and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the

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pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendant's conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendant's conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Bextra® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendant's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the

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claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b), and should be dismissed.

Fifty-fifth Defense

55. Defendant states on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendant states on information and belief that any injuries, losses, or damages suffered by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendant. Therefore, Plaintiffs' recovery against

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Defendant, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendant, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiffs' claims.

V.

PRAYER

WHEREFORE, Defendant prays for judgment as follows:

1. That Plaintiffs take nothing from Defendant by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendant be awarded its costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses, or damages is attributable to each person;
5. That any judgment for damages against Defendant in favor of Plaintiffs be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' injuries and damages; and
6. That Defendant have such other and further relief as the Court deems appropriate.

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April 2, 2008

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JURY DEMAND

Defendant Pfizer Inc. hereby demands a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

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